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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,781

02/04/2004

Jerry B. Gin

1375-0001.20

2376

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7590

07/10/2008

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
1400 PAGE MILL ROAD
PALO ALTO, CA 94304-1124

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

07/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/772,781	Applicant(s) GIN ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31-100 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 14-22, 27, 31-45, 49-54, 58-71 and 75-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12, 13, 23-26, 28, 29, 46-48, 55-57 and 72-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed April 10, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – New Matter (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 100 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites the limitation “substantially dissolvable”. There appears to be no support for this phrase in the originally filed instant disclosure.

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

Claims 9 and 100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The term "substantially" in claim 100 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term substantially makes dissolve indefinite because it cannot be determined what is encompassed by "substantially dissolved".

2) Claim 12 is indefinite insofar as it recites "form of claim, wherein". It cannot be determined from which claim the instant claims depends making it indefinite.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1-8, 12-13, 23-25, 30, 46-48, 72 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alderman et al. (US 4,528,125). The rejection is maintained and further applied to claim 100.

Applicant's Arguments

Applicant argues Alderman does not teach or suggest a lozenge that includes a sustained release wet matrix. Rather, Alderman discloses an aqueous dispersion that includes a) cellulose ether, which is dispersed as a plurality of finely divided cellulose

ether particles into a continuous aqueous phase, and b) a fragrance that is reversibly diffused in the cellulose ether particles. The Applicants contend that an aqueous dispersion of fine particles that include a fragrance adsorbed thereto is not equivalent to the lozenge containing a matrix as claimed by the applicants. Further, the Applicants contend that Alderman does not teach a matrix because Alderman actually teaches away from a sustained release matrix system. According to the MPEP § 2145, a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness. Alderman teaches away from the claims because Alderman discloses that dispersions are advantageous over sustained release matrix systems, such as those instantly claimed by the Applicants, because in a dispersion, as contrasted with a matrix system, the fragrance is more uniformly distributed therein and the physical form of the dispersion allows for a wide variety of uses that are not available in conventional, e.g., matrix based, sustained release systems. Therefore, in view of the above, Alderman does not teach or suggest all the elements of the rejected claims. Accordingly, a prima facie case of obviousness has not been established because Alderman does not teach or suggest all the elements of the rejected claims. This argument is not persuasive.

Examiner's Response

Applicant has not defined what is meant by "wet matrix". According to Merriam Webster, a matrix is 1: something within or from which something else originates, develops, or takes form; or 3 a: the natural material (as soil or rock) in which something

(as a fossil or crystal) is embedded **b**: material in which something is enclosed or embedded (as for protection or study). The reference discloses the oil is diffused into the ethylcellulose particle, thereby wetting the particles and forming a wet matrix. These particles are dispersed in an aqueous solution yet they may still be considered a "wet matrix". Especially considering the flavorings may comprise 0.1 to 200% based on the weight of the cellulose and the flavoring is diffused in the cellulose. It may also be argued that the particles are enclosed into the liquid which would also constitute a "wet matrix". It may be concluded that the dispersion itself is a wet matrix. Although the reference discloses the compositions are different from matrix systems, it specifically recites solid matrix compositions and all "matrix", "gel matrix" or "wet matrix" compositions. Therefore the reference does not really teach away from the claimed invention. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 26, 28-29 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alderman et al. (US 1-8, 12-13, 23-25, 30, 46-48, 72 and 73) as previously applied to claims 1-8, 12-13, 23-25, 30, 46-48, 72 and 73 in further view of Ventouras (US 6,183,775).

Alderman et al. disclose sustained release compositions comprising alkylcelluloses, preferably ethylcellulose and a fragrance. Ethyl cellulose is a polymer that is used to control the rate of release of and active agent (see Friedman et al.

discussed above). The compositions may be formulated into lozenges (col. 6, lines 50-54). The flavorings include peppermint oil. Flavorings comprise 0.1 to 200 percent based on the weight of the cellulose ether (col. 5, lines 30-33). In regards to the wet matrix, based on the ratio of flavoring agent to cellulose ether, it may be concluded the amount of flavor oil would give the properties of a wet matrix as defined by Applicant. In regards to claims 5-7 reciting a viscosity range from 1 to 120 cP as determined at 25°C using a 5% wt. aqueous solution of ethylcellulose, this is an inherent characteristic of commercially available ethylcellulose (see footnote 1), encompassing claims 5-7. Pigments, fillers, preservatives and water soluble polymers may also be included in the compositions (col. 5, lines 34-68), encompassing claims 46 and 47. The reference differs from the instant claims insofar as it does not disclose the lozenge comprises a sweetener.

Ventouras discloses a controlled release lozenge having organoleptic properties. The lozenge comprises fillers including xylitol, mannitol and sorbitol (which are non sugar sweeteners); an insoluble film forming agent which is capable of forming an insoluble matrix including ethyl cellulose and a swellable polymer including xanthan gum and cellulose derivatives (see Abstract). Auxiliaries are used in the compositions including aromas, sweeteners, colorants, buffering agents and preservatives. The reference differs from the instant claims insofar as it does not disclose the compositions comprise a "wet matrix" of ethyl cellulose and a flavoring agent and a range for the amount of flavoring agent that may be added to the compositions.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to use sweeteners in the compositions of the primary reference motivated by the desire to use components for their desired functions such as a sweetening agent as well as a filler.

Obvious-Type Double Patenting (Previous Rejection)

Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-16 and 23 of copending Application No. 11/904420. Applicant has requested the rejection be held in abeyance until allowable subject matter is found.

Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 are rejected.

Claims 9-11, 14-22, 27, 31-45, 49-54, 58-71 and 75-99 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612
/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612